that the balance of the equities favored an injunction. The injunction states:

> 1. During the Injunction Term . . . the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 . . .
> 2. Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR . . .
> 3. The Defendants shall not impose a "medical necessity" requirement or form for the filling of prescriptions of Namenda IR during the Injunction Term.

S.A. 137-38. The injunction is effective from the date of issuance, December 15, 2014, until "thirty days after July 11, 2015 (the date when generic memantine will first be available) (the 'Injunction Term')." S.A. 138. Defendants timely appealed the grant of the preliminary injunction, and we granted expedited review.

DISCUSSION

We review a district court's grant of a preliminary injunction for abuse of discretion. *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 116 (2d Cir. 2009). A district court has abused its discretion if it based its ruling on an error of law or a clearly

erroneous assessment of the evidence, or if its "decision . . . cannot be located within the range of permissible decisions." *Id.* (internal quotation marks omitted). We review legal conclusions, such as the appropriate standard for relief, *de novo*. *See Somoza v. N.Y.C. Dep't of Educ.*, 538 F.3d 106, 112 (2d Cir. 2008).

On appeal, Defendants argue that (1) the district court applied the wrong legal standard for a preliminary injunction; (2) product switching is not anticompetitive or exclusionary under § 2 of the Sherman Act; (3) Defendants' patent rights foreclose antitrust liability; (4) the agreement with Foundation Care does not violate § 1 of the Sherman Act; (5) New York failed to show irreparable harm; and (6) the injunction is vague and overbroad.

I. The Applicable Preliminary Injunction Standard

Defendants argue that the district court erred by applying the ordinary standard for a preliminary injunction, rather than a heightened standard, because the injunction provides New York with "substantially all the relief sought." Defendants' Brief ("Defs. Br.") at 25. We agree that a heightened standard applies.

Section 16 of the Clayton Act entitles a party to obtain injunctive relief "against threatened loss or damage by a violation of the antitrust laws." *California v. Am. Stores Co.*, 495 U.S. 271, 280 (1990) (quoting 15 U.S.C. § 26). A party seeking a preliminary injunction must ordinarily establish (1) "irreparable harm"; (2) "either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party"; and (3) "that a preliminary injunction is in the public interest." *Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotation marks omitted).

We have held the movant to a heightened standard where: (i) an injunction is "mandatory," or (ii) the injunction "will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 33-34 (2d Cir. 1995). When either condition is met, the movant must show a

"clear" or "substantial" likelihood of success on the merits, *Beal v. Stern*, 184 F.3d 117, 123 (2d Cir. 1999), and make a "strong showing" of irreparable harm, *Doe v. N.Y. Univ.*, 666 F.2d 761, 773 (2d Cir. 1981), in addition to showing that the preliminary injunction is in the public interest.

The injunction issued by the district court in this case remains in place until 30 days after generics enter the market, and therefore "grant[s] plaintiffs substantially all the relief they ultimately sought, in effect, as if the injunction had been permanent." *Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988). The district court found that Defendants' plan is contingent on switching patients to Namenda XR before generic IR enters the market. S.A. 20. The injunction, however, bars Defendants from withdrawing IR, and thus forcing a switch, "until thirty days after July 11, 2015 (the date when generic memantine will first be available)." S.A. 138. Because the injunction prevents Defendants' hard switch from succeeding, the injunction "render[s] a trial on the merits largely or partly meaningless." *Tom Doherty*

Assocs., 60 F.3d at 35.[17] Accordingly, the heightened standard applies.

That conclusion, however, is of little import in this case because New York has satisfied the heightened standard. The district court did not abuse its discretion in granting a preliminary injunction because New York has demonstrated a substantial likelihood of success on the merits of its monopolization and attempted monopolization claims under § 2 of the Sherman Act, *see Beal*, 184 F.3d at 123, and has made a strong showing that Defendants' conduct would cause irreparable harm to competition in the memantine-drug market and to consumers, *Doe*, 666 F.2d at 773. The district court's factual findings, which were based, for the most part, on Defendants' own internal documents, cannot be said to be clearly erroneous, and its injunction prohibiting Defendants from withdrawing Namenda IR prior to generic entry was not an abuse of discretion as being outside the range of permissible decisions.

[17] Although New York also seeks a permanent injunction, disgorgement, civil penalties, and damages, the preliminary injunction is the gravamen of the complaint.

II. Monopolization and Attempted Monopolization Under § 2 of the Sherman Act

Section 2 of the Sherman Act makes it an offense to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2; *see also Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 495 (2d Cir. 2004). To establish monopolization in violation of § 2, a plaintiff must prove not only that the defendant possessed monopoly power in the relevant market, but that it willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Id.* In order to show attempted monopolization, the plaintiff must prove: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and

(3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Attempted monopolization, unlike monopolization, requires a finding of specific intent. *See, e.g., Delaware & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 180 (2d Cir. 1990).

Defendants' patents on Namenda IR indisputably grant them a legal monopoly in the U.S. memantine-drug market until July 11, 2015.[18] The parties do not dispute the district court's factual findings that the relevant market is the memantine-drug market in the United States and that Namenda IR and XR represent 100% of that market. S.A. 108-10. Consequently, the parties do not dispute that Defendants possess monopoly power. *See Geneva Pharm.*, 386 F.3d at 500 (monopoly power can be "proven directly through evidence of control over prices or the exclusion of competition," or "inferred from a firm's large percentage share of the relevant market").

Given that Defendants' monopoly power has been established, this case turns on whether Defendants willfully sought

[18] *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market.").

to maintain or attempted to maintain that monopoly in violation of § 2. In *United States v. Microsoft Corp.*, 253 F.3d 34, 58-60 (D.C. Cir. 2001) (en banc), the D.C. Circuit, sitting en banc, established a helpful framework for determining when a product change violates § 2 based on the rule-of-reason test articulated by the Supreme Court in *Standard Oil Co. v. United States*, 221 U.S. 1 (1911), and generally applied to antitrust claims. *See also Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 289-90 (2d Cir. 2006) (explaining that courts analyze most antitrust claims under the rule of reason).[19] Under the *Microsoft* framework, once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer "nonpretextual" procompetitive justifications for its conduct. 253 F.3d at 58-59. The plaintiff may

[19] *See also Mid-Texas Commc'ns Sys., Inc. v. Am. Tel. & Tel. Co.*, 615 F.2d 1372, 1389 n.13 (5th Cir. 1980) ("It is clear, however, that the analysis under section 2 is similar to that under section 1 regardless whether the rule of reason label is applied per se." (citing *Byars v. Bluff City News Co.*, 609 F.2d 843, 860 (6th Cir. 1979))); *Cal. Computer Prods., Inc. v. Int'l Bus. Machs. Corp.*, 613 F.2d 727, 737 (9th Cir. 1979) ("[U]nder § 2 attempt as with § 1 monopolization individual conduct is measured against the same 'reasonableness' standard governing concerted and contractual activity under § 1.").

then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit. *Id.*

a. Anticompetitive and Exclusionary Conduct

"As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *Microsoft*, 253 F.3d at 65; *see also Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 544-45 (9th Cir. 1983). Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of "exclusionary or anticompetitive effects" in order to "distinguish 'between conduct that defeats a competitor because of efficiency and consumer satisfaction'" and conduct that impedes competition through means other than competition on the merits. *Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d 186, 188-89 (2d Cir. 1992) (quoting *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1359 (2d Cir. 1988)).

Well-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes

competition.[20] The leading case in our circuit for § 2 liability based on product redesign is *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603

[20] Our emphasis on consumer coercion in evaluating a monopolist's product redesign is in accord with several of our sister circuits. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 994 (9th Cir. 2010) ("A monopolist's discontinuation of [an old product] may violate § 2 if it effectively forces customers to adopt its new [product]."); *Microsoft*, 253 F.3d at 65 (explaining that Microsoft's redesign of its operating system was anticompetitive because the redesign impeded competition "not by making Microsoft's own browser more attractive to consumers but, rather, by discouraging [manufacturers] from distributing rival products"); *cf. Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 63 F.3d 1540, 1550 (10th Cir. 1995) (noting that illegal tie-ins under Section 1 may "qualify as anticompetitive conduct for Section 2 purposes"). Similarly, the other district courts that have considered product hopping cases also examined consumer coercion. And those district courts that have ruled in favor of plaintiffs alleging antitrust violations stemming from product hopping have found consumer coercion. *See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663, at *12 (E.D. Pa. Dec. 3, 2014) (plaintiffs alleged exclusionary conduct under § 2 where the brand manufacturer coerced patients into switching from the tablet form of a drug—for which their patent was set to expire—to a new film version of the drug by raising allegedly false safety concerns about the tablet and announcing that it would soon be withdrawn from the market); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) (plaintiffs alleged antitrust violations where the defendants introduced new drug formulations and withdrew the prior versions whose exclusivity period would soon expire). In contrast, in cases in which there is no evidence of coercion, district courts have rejected such claims. *See Mylan Pharm. Inc. v. Warner Chilcott PLC et al.*, No. Civ. 12-3824, 2015 WL 1736957, at *13 (E.D. Pa. Apr. 16, 2015) (noting that because generics had already entered the market at the time of defendants' product reformulation, "doctors remained free to prescribe generic Doryx; pharmacists remained free to substitute generics when medically appropriate; and patients remained free to ask their doctors and pharmacists for generic versions of the drug"); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (dismissing a case alleging attempted market monopolization because unlike in *Abbott Labs*, "there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca . . . introduced a new drug to compete with already-

F.2d 263 (2d Cir. 1979). In that case, Kodak simultaneously introduced its new Kodacolor II film and new Kodak 110 camera, which was designed so that it could only be used with the Kodacolor II film (the "110 system"). *Id.* at 277-78. Kodak, which possessed a lawful monopoly in film but not in cameras, heavily advertised Kodacolor II film as "a remarkable new film," and for 18 months, Kodak made Kodacolor II film only for the 110 camera. *Id.* at 278. Berkey Photo, Inc. ("Berkey"), a smaller camera manufacturer, alleged that Kodak unlawfully used its monopoly in film to increase camera sales and monopolize the camera market. *Id.* We rejected that claim and held that the introduction of the 110 system and advertising of the Kodacolor II film did not violate the Sherman Act because "[Kodak's] success was not based on any form of coercion." *Id.* at 287. But, of significance to the case before us, we cautioned that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing

established drugs—both its own and others'—and with the generic substitutes for at least one of the established drugs").

film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." *Id.* at 287 n.39.[21]

In this case, Defendants argue that withdrawing a product is not anticompetitive or exclusionary conduct, especially when the new product is superior to the old product.[22] Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, *id.* at 287, and to impede competition, *id.* at 274-75, its actions are anticompetitive under the Sherman Act.[23] *Cf. Cont'l Ore*

[21] We also noted that restricting Kodacolor II to the 110 format for 18 months may have been anticompetitive conduct, but we did not decide the question because there was no proof of injury to Berkey. *Berkey Photo*, 603 F.2d at 290.

[22] Whether XR is superior to IR is not significant in this case. When there is coercion, "the technological desirability of the product change . . . bear[s] on the question of monopolistic intent," *id.* at 287 n.39, rather than the permissibility of the defendant's conduct. Here, there is no genuine dispute that Defendants intended to avoid the patent cliff. *See, e.g.*, J.A. 132, 155.

[23] Several other courts have held that product redesign violates § 2 when combined with other conduct and the combined effect is anticompetitive or exclusionary. *See Allied Orthopedic*, 592 F.3d at 1000 (explaining that § 2 is violated when "some conduct of the monopolist associated with its introduction of a new and improved product design constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market" (internal quotation marks omitted)); *In re Suboxone*, 2014 WL 6792663, at *10 ("The key question is whether

Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962) (noting that when an antitrust conspiracy involves multiple acts, "[t]he character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole" (internal quotation marks omitted)). Here, Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.

i. Consumer Coercion

Defendants' hard switch crosses the line from persuasion to coercion and is anticompetitive. As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and

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the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit.").

with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.

By effectively withdrawing Namenda IR prior to generic entry, Defendants forced patients to switch from Namenda IR to XR—the only other memantine drug on the market.[24] S.A. 49; Tr. 183:22-184:17 (Stitt) ("So the unique thing [about the Namenda IR hard switch] I think is that there's really no place for prescribers to, to go with a drug to treat that condition."). In fact, the district court found that Defendants devised the hard switch because they projected that only 30% of memantine-therapy patients would voluntarily switch to Namenda XR prior to generic entry. S.A. 56-57. Defendants' hard switch was expected to transition 80 to 100% of Namenda IR patients to XR prior to generic entry, S.A. 81, and thereby impede generic competition.

Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of *Berkey*

[24] As previously noted, the other available Alzheimer's drugs, all CIs, are not substitutes for Namenda because they perform different medical functions and are not designed to treat moderate-to-severe Alzheimer's disease.

Photo's basic tenets: the market can determine whether one product is superior to another only "so long as the free choice of consumers is preserved." 603 F.2d at 287. Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice. In this way, Defendants could avoid competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer's patients to take XR,[25] with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.

ii. Impedes Competition

As the district court concluded, Defendants' hard switch would likely have anticompetitive and exclusionary effects on

[25] Alternatively, patients could discontinue memantine-therapy entirely.

competition in the memantine market, creating a "dangerous probability" that Defendants would maintain their monopoly power after generics enter the market. *Spectrum Sports*, 506 U.S. at 456. Based on careful consideration of the unique characteristics of the pharmaceutical market, the district court found that "[p]rice competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States." S.A. 26.

We agree with the district court's analysis. Forcing patients to switch to XR would prevent generic substitution because generic versions of IR are not AB-rated to Namenda XR. And if, as Defendants' own internal predictions estimate, the hard switch successfully converted 80 to 100% of IR patients to XR prior to generic entry, there would be "few to no prescriptions" left for which generics would be eligible to compete. S.A. 82. Because Defendants' forced switch "through something other than competition on the merits[] has the effect of significantly reducing

usage of rivals' products and hence protecting its own . . . monopoly, it is anticompetitive." *Microsoft*, 253 F.3d at 65.

Defendants and their *amici* argue that generics can successfully compete by persuading third-party payors and prescription-benefit managers to promote generic IR through the use of formularies, tiered-drug structures, step programs, and prior-authorization requirements.[26] But, as the district court determined, competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers.[27]

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[26] Formularies, tiered-drug structures, step programs, and prior-authorization requirements are all tools that third-party payors may use to incentivize patients to take less-expensive drugs. A formulary is a list of approved drugs that a health plan will pay for, either in whole or in part. S.A. 19. A tiered-drug structure divides the drugs listed on a plan's formulary into categories or "tiers." S.A. 20. Typically, health plans use a three-tiered system, which reserves tier 1 for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. The portion of the cost of the drug that the patient is responsible for paying, known as the "co-payment" or "co-pay," increases with each tier. A step program requires a patient to first try a preferred, and usually less expensive, drug. Only if that treatment is unsuccessful will the health plan pay for the patient's drug of choice. S.A. 20. A prior authorization policy requires a patient to obtain the third-party payor's approval for payment prior to taking a particular drug. Antitrust Economists Br. at 14.

[27] The district court found that the regulatory context makes it impractical and uneconomical for generic manufacturers to market their products to doctors or pharmacists because, among other reasons, marketing costs severely impact generic manufacturers' ability to offer the lower prices upon which they compete. S.A. 78. Two other district courts confronted with product hopping cases concluded that plaintiffs plausibly alleged that the unique characteristics of

S.A. 78. For there to be an antitrust violation, generics need not be barred "from all means of distribution" if they are "bar[red] . . . from the cost-efficient ones." *Microsoft*, 253 F.3d at 64; *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."). Moreover, as the district court found, additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors.

Although in theory, Alzheimer's patients would be free to switch back to IR therapy after generic entry, the district court found that, in practice, such a reverse commute would be a highly unlikely occurrence. As one of Defendants' own executives explained during a January 21, 2014 earnings call: "if we do the hard switch and we

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the pharmaceutical industry "make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals." *In re Suboxone*, 2014 WL 6792663, at *12; *see also Abbott Labs.*, 432 F. Supp. 2d at 423 (same).

convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back." S.A. 51. This is because there are high transaction costs associated with reverse commuting. Any patient who wants to switch back to twice-daily IR therapy must first obtain a new prescription from a doctor. But, as the district court found, the nature of Alzheimer's disease makes moderate-to-severe Alzheimer's patients especially vulnerable to changes in routine, and makes doctors and caregivers very reluctant to change a patient's medication if the current treatment is effective. As a result, if Defendants forced patients to switch from twice-daily Namenda IR to once-daily XR, those patients would be very unlikely to switch back to twice-daily generic IR even if generic IR is more cost-effective.[28] Moreover, third-party payors are reluctant to require

[28] The Department of Health and Human Services ("HHS") reached this same conclusion, explaining:

> The unique nature of this patient population—Alzheimer's patients with moderate-to-severe dementia—makes it likely that a switch from the twice-daily Namenda IR to the once-daily Namenda XR would be a permanent one for practical purposes, as providers, patients, and families would be reluctant to switch back to twice-a-day therapy even if they believed that it represented a better value.

patients to switch from a drug they are currently taking to a new drug, so health plans would be unlikely to require patients to switch to less-expensive generic IR.

Defendants and their *amici* argue that the district court's focus on AB-ratings is misplaced because up to 20 states do not impose an AB-rating requirement and thus "*may* let pharmacists unilaterally substitute generic IR for Namenda XR." Defs. Br. at 13 (emphasis added). Defendants' argument, however, exaggerates the variance in state substitution laws. Many states that do not explicitly require generic drugs to have the same AB-rating effectively require the same degree of therapeutic equivalence. For example, Defendants cite Iowa Code § 155A.32 as an example of a state law that "do[es] not rely on the Orange Book." Defs. Br. at 13. Section 155A.32(1) permits pharmacists to substitute a generic drug if it has the same "demonstrated bioavailability" as the brand drug, Iowa Code Ann. § 155A.32(1), but Section 155A.3(9) clarifies that a generic is only

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HHS, Office of the Assistant Sec'y for Planning and Evaluation, *Some Observations Related to the Generic Drug Market* 5 (2015), *available at* http://aspe.hhs.gov/sp/reports/2015/GenericMarket/ib_GenericMarket.pdf (HHS, *Some Observations*).

considered to have the same "demonstrated bioavailability" if it has the same "rate and extent of absorption of a drug or drug ingredient from a specified dosage form," Iowa Code Ann. § 155A.3(9). Because the dosage and absorption rates of generic IR differ from that of XR, the drugs are not bioequivalent under Iowa law. Moreover, because generic IR is manufactured in tablet form and Namenda XR is marketed in capsule form, they do not have the same dosage form.[29] As a result, as in New York and the 29 other states that require an AB-rating, Iowa pharmacists will not be permitted to substitute generic IR for XR.[30]

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[29] Generic IR is manufactured in 5 and 10 mg tablet dosage formulations whereas Namenda XR is marketed in 7, 14, 21, and 28 mg capsule dosage formulations. J.A. 673 n.57. As Dr. Ernest R. Berndt, Ph.D. explains in his declaration, "tablets and capsules are not the same 'dosage form.'" *Id.*

[30] Defendants argue that up to 20 states may allow pharmacists to substitute generic IR for Namenda XR; however, throughout their briefs, Defendants and their experts point to 21 different states. Of the states identified by Defendants and their experts, 16 require the same dose and/or dosage form and thus will not allow generic IR to be substituted for Namenda XR. *See* Ala. Code § 34-23-8; Alaska Stat. Ann. §§ 08.80.295(a), 08.80.480(11); Ark. Code Ann. §§ 17-92-503(a)(1), 17-92-101(6), (11); Cal. Bus. & Prof. Code §§ 4073(a), 4052.5(a), (f); Colo. Rev. Stat. Ann. §§ 12-42.5-122(1)(a), *as amended by* 2015 Colo. Legis. Serv. Ch. 77 (S.B. 15-071), 12-42.5-102(40); Conn. Gen. Stat. Ann. § 20-619(b); Fla. Stat. Ann. §§ 465.025(2), (1)(b); Ga. Code Ann. § 26-4-81(a); Mo Ann. Stat. § 338.056(1); Mont. Code Ann. § 37-7-505(1); Neb. Rev. Stat. §§ 71-5403(1), 71-5402(1), (5), (6), *as amended by* 2015 Nebraska Laws L.B. 37; N.C. Gen. Stat. Ann. §§ 90-85.28(a), 90-85.27(1); Or. Rev. Stat. Ann. § 689.515(2)(a); R.I. Gen. Laws Ann. §§ 21-31-16.1(a), 5-19.1-2(k); S.C. Code Ann. § 39-24-30a. Mich. Comp. Laws Ann. § 333.17755(1)

Defendants argue that their conduct was not anticompetitive because preventing "free riding" is a legitimate business purpose. But what Defendants call "free riding"—generic substitution by pharmacists following the end of Namenda IR's exclusivity period—is authorized by law; it is the explicit goal of state substitution laws; and it furthers the goals of the Hatch-Waxman Act by promoting drug competition, *Actavis*, 133 S. Ct. at 2228, and by preventing the "practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]," H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

Defendants also argue that antitrust law is not a vehicle for enforcing the "spirit" of drug laws. Defs. Br. at 46. But the Supreme

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allows for substitution of "generically equivalent" drugs, which courts in Michigan have interpreted to require "chemical equivalence," meaning that the drugs "contain the same active ingredients and are identical in strength, dosage form and route of administration." *Pennwalt Corp. v. Zenith Labs., Inc.*, 472 F. Supp. 413, 417 (E.D. Mich. 1979). Oklahoma prohibits substitution "without authority of the prescriber or purchaser," so we cannot determine whether generic IR will be substituted for Namenda XR under Oklahoma law. *See* Okla. Stat. Ann. tit. 59, § 353.13(D). Of the states that allow pharmacists to substitute generic drugs without consulting the prescribing physician, four states *may*—but will not necessarily—allow substitution of generic IR for Namenda XR. *See* Minn. Stat. Ann. § 151.21 Subd. 3; Minn. R. 9505.0340 Subp.3(H); N.D. Cent. Code Ann. §§ 19-02.1-14.1(3), (1)(g); Vt. Stat. Ann. tit. 18, § 4605(a), 4601(4); Wash. Rev. Code Ann. § 69.41.120; 69.41.110(4). Those four states account for less than 6% of the U.S. population. J.A. 673.

Court has made clear that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Trinko*, 540 U.S. at 411. Leading antitrust authorities have encouraged courts to acknowledge market defects, such as a price disconnect and the exclusivity of patents, in their antitrust analysis.[31] And in other Hatch-Waxman contexts, this court has recognized that efforts to manipulate aspects of the Hatch-Waxman incentive structure to exclude competition could state an antitrust claim. *See, e.g., Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 106 (2d Cir. 2010) ("[A] plaintiff can have antitrust claims" where a pharmaceutical manufacturer "manipulate[s] the [Hatch-Waxman-conferred] 180-day exclusivity period in a manner that bars subsequent challenges to the patent or precludes the generic

[31] *See* IIIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 776c, at 297 (3d ed. 2008); Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 25 (2012); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006) ("A particular regulatory regime sets the boundaries of feasible anticompetitive conduct."); Jonathan Jacobson, et al., *Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence*, 23 Loy. Consumer L. Rev. 1, 8 (2010) ("There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of networked markets . . . and (b) in pharmaceutical markets . . . .").

manufacturer from marketing non-infringing products unrelated to the patent."), *abrogated on other grounds by Actavis*, 133 S. Ct. at 2231. Therefore, we conclude that the district court appropriately considered the unique market characteristics of the pharmaceutical industry in concluding that antitrust law "requires [Defendants] to allow generic competitors a fair opportunity to compete using state substitution laws." S.A. 95-96.

b. Procompetitive Justifications

All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, "trying to . . . put up barriers or obstacles" to generic competition. J.A. 132; *see also* S.A. 49 ("We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity."); J.A. 155 ("[W]hat we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base

users."); S.A. 49 ("Our mission is to convert to Namenda XR and lift the franchise . . . . We need to convert as much IR business to Namenda XR as quickly as possible."). Based largely on Defendants' own documents, New York has rebutted Defendants' procompetitive justifications.

c. Procompetitive Benefits v. Anticompetitive Harms

Because we have determined that Defendants' procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms. But in any event, New York has shown that whatever procompetitive benefits exist are outweighed by the anticompetitive harms. Defendants argue that their conduct is procompetitive because "[l]aunching a new product . . . advances competition by adding a better product to the market and by paving the way for further innovation." Defs. Br. at 51. While *introducing* Namenda XR may be procompetitive, that argument provides no procompetitive justification for *withdrawing* Namenda IR.

Defendants argue that withdrawing IR was procompetitive because it would maximize their return on their investment in XR.

But in deciding to take IR off the market, Defendants were willing to give up profits they would have made selling IR—Forest's best-selling drug. This "willingness to forsake short-term profits to achieve an anticompetitive end" is indicative of anticompetitive behavior. *In re Adderall*, 754 F.3d at 135 (internal quotation marks omitted). Moreover, Defendants fail to explain why the potential [redacted] in additional XR sales that they stood to earn—which is less than the approximately $1.5 billion in annual sales they have made from Namenda IR in recent years—makes economic sense in the absence of the benefit derived from eliminating generic competition. *See id.* at 133 (stating that anticompetitive effects could be shown where defendants' conduct "makes sense only because it eliminates competition"). As a result, we agree with the district court that:

> Defendants' short-term loss of [redacted] in IR sales, translating to [redacted] in income, is most rationally construed as an investment in moving the memantine market in [their] favor [through impeding generic competition], yielding [D]efendants [redacted] in income over the course of the next [redacted].

S.A. 74.

Finally, Defendants have presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation. To the contrary, as the American Antitrust Institute *amici* argue, immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.

In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.

III. Patent Rights as a Defense to Liability

Defendants argue that their patent rights under Namenda IR and Namenda XR shield them from antitrust liability. To be sure,